Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 33D1036314	**(X3) Date Survey Completed** 10/09/2019
Name of Provider or Supplier Karen F Schwartz Md Pc	**Street Address, City, State** 165 Froehlich Farm Blvd, Woodbury, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor's review of the manufacturer's packet inserts for Siemens Multistix and Clinitek Status analyzer, the manufacturer's packet insert for DCA Vantage HgbA1c analyzer and an interview with the testing person, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new vial of the urine Multistix opened and performing two levels of external quality controls for each new lot of test cassettes for HgbA1c on the DCA Vantage analyzer. FINDINGS: 1. The packet insert for the urine Multistix requires that external controls be performed with each new Vial of Multistix opened. On October 9, 2019 at approximately 11:00 AM the testing person confirmed surveyor's findings that documentation for the required external control testing was not available from July 25, 2018 through October 8, 2019. 2. The packet insert for the DCA Vantage HgbA1c analyzer and test cassettes requires that external controls be performed with each new lot and/or shipment of test cassettes opened. The testing person confirmed surveyor's findings that the laboratory did not perform the required external QC for HgbA1c from July 25, 2018 through October 6, 2019. 3. Approximately 150 patients specimens were tested and reported for urinalysis and approximately 150 patient specimens were tested and reported for HgbA1c during this time frame.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's observation of the laboratory's testing area and an interview with the laboratory testing person, the laboratory failed to discontinue the use of expired testing materials. FINDINGS: 1. On October 9, 2019 at approximately 11:30 AM the testing person confirmed surveyor's findings that the laboratory used an expired urine pregnancy Imco kit lot # 1611099 expiration date October 2018. 2. The above expired Imco kit was used to test urine pregnancy testing for approximately 10 patients from November 2018 to the date of this survey.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality assessment (QA) program and confirmed in an interview with the testing person at the time of the survey, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to D1001, D5417